Claim Rejections:

The newly added claims eliminate the objections made by the Examiner by the applicant specifically limiting claims so that the claims distinguish over the references cited. Specifically the claims eliminate the use of ELISA, Western Blot and Thin Layer Liquid Phase methods for analysis of HIV antibodies to be used to as claimed by Friedman-Kein et al., and Ishigawa et al. This places the application in condition for allowance.

For all of the above reasons, applicant submits that the specification and claims are now in proper form, and that the newly added claims 19-32 all define patentably over the prior art. Therefore the applicant submits that this application is now in condition for allowance, which action is respectfully solicited.

Comments:

REMARKS - General

The applicant has added new claims 19-32 to define the invention more particularly and distinctly so as to overcome the rejections and define the invention patentably over the prior art.

The Claims Rejection Under 35 USC § 103

The prior claims which are now deleted, were rejected under 35 U.S.C. § 103(a) as being unpatentable over Friedman-Kien et al. and Ishigawa et al. The Friedman-Kien device describes the antiquated methods of Western Blot and ELISA. These two methods as mentioned in the specification are antiquated and have no structural, functional, or method of use resemblance in any form to the current device. The use of this reference is perplexing to the applicant in that the applicant taught these antiquated references in the original specification. The Ishikawa reference is even more perplexing, this is a device that has never made it to market and is nothing more than a paper patent. However, this device as claimed, is a circulation thin layer liquid phase assay that requires a pool of

reaction liquid, glass or plastic tubes, spectrophotometers, etc., for trapping an analyte in a reaction mixture.

The following requirements of the reference (Friedman-Kien) for analysis by Western Blot (1-5) & ELISA(6-11):

1) The urine sample has to be **substantially** concentrated.
2) The use of high currents of electricity required by gel electrophoresis.
3) The transfer of separated proteins to a suitable solid support.
4) Incubation.
5) And HOURS is technical time.
6) Microtiter plates.
7) Spectrophotometer.
8) Electricity.
9) Specimen diluent.
10) Bead incubation for 16 to 22 hours at room temperature.
11) 60 to 90 minutes if the urine is already concentrated, therefore, hours.

The reference (Ishikawa) requirements for analysis:

1) Ball type solid phase in **Rotation**.
2) Reaction liquid pool.
3) Coated surface with solid phase.
4) Test tube (rotating) on some sort of Rotating Device.
5) Transfer and permeation (?) of a reaction liquid.

The present art requirements for analysis:

1) Random urine approximately 3 to 5 drops.
2) About 3 minutes of technical time.

What the present art **does not** require for analysis:

1) No Incubation.

2) **No** electricity.

3) **No** transfer of separated proteins.

4) **No** gel electrophoresis to include cells, wires, power supply, etc.

5) **No** Western Blot techniques or requirements.

6) **No** ELISA techniques.

7) **No** spectrophotometer.

8) **No** microtiter plates, etc.

9) **No** rotator or rotating tubes.

10) **No** reaction liquid pool.

11) **No** rotating ball.

12) **No** transfer and permeation of liquid, etc.

Of course, the obvious stands out that the present art is a **marked** advancement over the prior art goes without saying. The savings in time, money, components, etc., alone, are enormous. Because applicant's newly added claims 19-32 recite novel physical features (over the cited prior art and the novel physical distinctions of claims 19-32 are unobvious under § 103(a) for the following reasons. The present device produces **unexpected results** due to the inherent design and capability differences between the inventions. When the devices are juxtapose the results produced are unexpected. The present device is a single step method for the analysis of HIV antibodies in urine or other fluids effectively allowing **superior** results with reference to time, cost, and accuracy. The present device requires **no pretreatment, no Western Blot, no ELISA, no rotating ball, no reacting liquid pool, no permeation of liquid, etc.,** as required by the Friedman-Kien and Ishikawa devices. Friedman-Kien and the Ishikawa devices are complicated, multiple step, and tedious methods for the analysis of HIV and are not an advancement in the art as the case with the Smith patent. The limitations of Friedman-Kien and Ishikawa as mentioned do not allow for the **unsuggested** and **superior** capability of the present device. Without a showing in the Smith patent that a

complicated device with multiple steps for the measurement of HIV antibodies is required (which there is none) then the newly added limited claimed should be allowed. The present device **omits elements** certain, multiple, and critical elements of the Friedman-Kien and Ishikawa devices, namely the present art does not require all of the above as mentioned: pretreatment, electrophoresis, electrophoresis cells, wires, and power supplies, rotator, spectrophotometer, rotating ball, liquid reaction pools, incubation, protein transfer to another media, etc. The present art by not including these elements of the prior art is in fact more capable of producing a result faster and without the use of electricity enables it to be used in Third World countries, etc. Without question the present art's method for the presence of HIV antibodies in urine or other fluids is a **superior** functional device with reference to time, money, and physical requirements. The prior art of Friedman-Kien and / or Ishikawa do not explain any of the present arts novel features nor anticipate any of the novel features of the present art. There is no reference made by Friedman-Kien and Ishikawa to the present art. Therefore, the present art could not have been, nor has it been rendered obvious by the prior art of Friedman-Kien and Ishikawa. The applicant's invention **solves a different problem** (detection of HIV antibodies in urine using a single step) that the reference cannot, and such a solution to the different problem is recited in the newly added and amended claims.

Thus the applicant submits that their invention clearly recites novel physical subject matter, which distinguishes over any possible combination or use of Friedman-Kien and Ishikawa.

The Newly Added Novel Physical features of Claims 19-32 Produce New And Unexpected Results And Hence Are Unobvious And Patentable Over The Reference Under § 103.

Again, reconstruction of an invention using Friedman-Kien and Ishikawa to support a rejection under 35 U.S.C. 103 is improper as clearly set forth by the Court of Appeals For the Federal Circuit in *In re Fritch*, 23 USPQ 2d 1780 at 1783-1784 (CAFC

1992) where it is stated, "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination" ..... ". It is impermissible to use the claimed invention as an instruction manual or `template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This Court has previously stated that `[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures of the prior art to deprecate the claimed invention'."

Applicant's invention of newly added and limited claims 19-32 are not obvious when compared to the prior art of Friedman-Kien and Ishikawa because such prior art as a whole does not teach applicant's invention. Rather, some of the prior art teaches various aspects of detection of HIV antigens and antibodies which are in no manner even slightly similar to the present art. Furthermore, no suggestion is made by any of the prior inventors to combine any of these prior art elements to form applicants' device. For these reasons applicant is entitled to allowance of newly added and limited claims 19-32.

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. **Under section 103**, teachings of references can be combined only if there is some suggestion or incentive to do so." In re Fritch, 23 USPQ 2d 1780, 1783 (CAFC 1992).

Friedman-Kien and Ishikawa, nor any other prior art separate from applicants' disclosure, suggests that these references be combined, much less be combined in the manner proposed. The proposed combination would not be physically possible or operative. The combination of the referenced prior art to produce the present art is not physically or feasibly possible. Even if Friedman-Kien and Ishikawa were to be combined in the manner proposed, the proposed combination would not show all of the novel physical and functional features of newly added limited claims 19-32 because the combination is impossible and impractical.

"In order to establish a ***prima facie*** case of the obviousness, it is necessary for the examiner to present ***evidence***, preferable in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art ***would have been led*** to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. ...That which is within the capabilities of one skilled in the art is not synonymous with obviousness. ... That one can ***reconstruct*** and/or explain the theoretical mechanism of an invention by mean of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a ***prima facie*** case of obviousness only by showing some objective teaching in either prior art, or knowledge generally available to one of ordinary skill in the art, that 'would lead' that individual 'to combine the relevant teachings of the references.' ... Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the ***motivating force*** which would impel one skilled in the art to do what the ***applicant has done."***

In the present case, there is no reason to support the proposed combination of Friedman-Kien and Ishikawa. However the fact that both references teach a device that is supposed to be used in the detection of HIV is not sufficient to **gratuitously and selectively** substitute parts of one reference for a part of another references in order to attempt to meet applicants' novel claimed invention.

Even if the Prior Art References Were To Be Combined In The Manner Proposed, The Proposed Combination Would Not Show All Of The Novel Physical and Functional Features Of The Claims

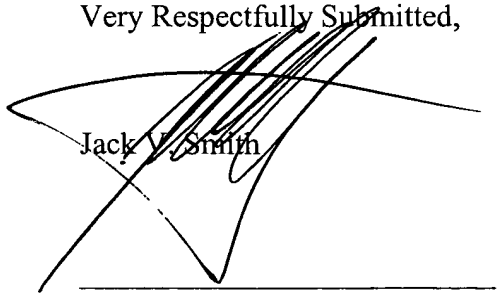
Conclusion

For all of the above reasons, applicant submits that the specification and newly added and limited claims are now in proper form, and that the claims all define patentably over the prior art. Therefore the applicant submits that this application is now in condition for allowance, which action is respectfully solicited.

Conditional Request For Constructive Assistance

Applicants have amended the specification and claims of this application so that they are proper, definite, and define novel structure which is also unobvious. If, for any reason this application is not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to M.P.E.P. § 107.03(d) and § 707.07(j) in order that the undersigned can place this application in allowable condition as soon as possible and without the need for further proceedings.

Very Respectfully Submitted,



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signed Jack V. Smith